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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 05032004

Application Number: 09/616,843
Filing Date: July 14, 2000
Appellant(s): NASH ET AL.

Richard O. Bartz
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2/20/04.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

Claims 14, 15, 16, 27, 29, and 31 have been amended subsequent to the Final rejection.

Claims 17 and 18 have been canceled.

This appeal involves claims 14-16, 19-24, and 27-32 which can be found in the amendment after Final filed 9/23/03 or the Appendix A of the Examiner's Answer.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

The amendment after final rejection filed on 9/23/03 has been entered.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows:

The enablement, written description and new matter rejections (Issues A-B) of claims 14-16, 19-24, and 27-32 under 35 U.S.C. 112, First paragraph, is hereby withdrawn in view of Appellants' amendment filed on 9/23/03.

The issues on appeal are as follow:

Whether claims 14, 15 and 16 are unpatentable under 35 USC 103(a) over U.S. Pat No. 5,080,895 (Tokoro) in view of Karuse et al, U.S. Pat No. 5,585,098 (Coleman) and U.S. Pat No. 5,741,489 (Pimentol).

Whether claims 19-24 are unpatentable under 35 USC 103(a) over U.S. Pat No. 5,080,895 (Tokoro) in view of Karuse et al, U.S. Pat No. 5,585,098 (Coleman) and U.S. Pat No. 5,741,489 (Pimentol) and further in view of U.S. Pat No. 6,086,878 (Adalsteinsson et al) and U.S. Pat No. 4,166,847 (Betz).

Whether claims 27-32 are unpatentable under 35 USC 103(a) over U.S. Pat No. 5,080,895 (Tokoro) in view of Karuse et al, U.S. Pat No. 5,585,098 (Coleman) and U.S. Pat No. 5,741,489 (Pimentol) and further in view of U.S. Pat No. 6,086,878 (Adalsteinsson et al) and U.S. Pat No. 4,166,847 (Betz).

It is noted that appellant separates the second 103(a) rejection into issues D and E. Further, it is note that appellant's statement in issue E "...U.S. Pat No. **5,741,489** (Betz et al)." is not corrected. The correct US Pat No to Betz et al is U.S. Pat No. 4,166,847.

(7) Grouping of Claims

Appellant's brief includes a statement that the claims fall into three groups. The claims of Group I (claims 14-16), Group II (claims 19-24), and Group III (claims 27-32) do not stand or fall together. Each group of claims defines a distinct and novel method of promoting the growth of food animals.

However, the appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because Claims 19-24 and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Krause *et al* (of

record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892), US Pat No 5,585,098 (Dec 1996, PTO 1449) and US Pat No 5,741,489 (April 1998, PTO 892) as applied to claims 14-16 above and further in view of US Pat 6,086,878 (of record, Jul 2000, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892). Group II (claims 19-24) and Group III (claims 27-32) require the antibody in Group I (claims 14-16). Therefore, claims 14-16, 19-24 and 27-32 should stand or fall together.

(8) Claims Appealed

Claims 14-24, and 27-32 contain substantial errors as presented in the Appendix to the brief. Accordingly, claims 14-16, 19-24, and 27-32 are correctly written in the Appendix A to the Examiner's Answer or in the alternative, in the After Final amendment filed 9/23/03.

(9) Prior Art of Record

5,080,895	Tokoro	1-1992
5,585,098	Coleman	12-1996
5,741,489	Pimentel	4-1998
6,086,878	Adalsteinsson	07-2000
4,166,867	Betz	9-1979

Krause, D.O. "An rRNA Approach for Assessing the Role of Obligate Amino Acid-Fermenting Bacteria in Ruminal Amino Acid Deamination" Applied and Environmental Microbiology, Vol 62, no. 3 (Mar 1996), page 815-821

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892), US Pat No 5,585,098 (Dec 1996, PTO 1449) and US Pat No 5,741,489 (April 1998, PTO 892).

The '895 patent teaches a method of promoting the growth of food animals by preventing diarrhea (dietary protein wasting caused by diarrhea due to the presence of *E. coli*.) in livestock by inoculating an egg laying female birds such as hen against a selected immunogen such as bacteria *E. coli*. (See column 5, lines 29-30, in particular), after a period of time such as a few weeks after the inoculation, the reference hen becomes sensitive to the reference immunized immunogen and produces the specific antibody to the immunized immunogen in the yolk and the albumin of the eggs (See column 5, lines 47-60, column 6, 10-18, in particular). The reference method includes the steps of collecting the egg laid by the hen (See column 6, line 1, in particular), separating the antibody against the inoculated immunogen from the yolk or albumin or both which is the entire content of the egg (See column 6, lines 19-20, in particular), drying the separated egg antibody by the process such as spray drying or lyophilizing to from powder product (See column 6, line 24-25, in particular), distributing and supplying the resulting dried egg antibody product as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent teaches the method of making bird antibody to any bacteria of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

The claimed invention in claim 14 differs from the teaching of the reference only in that the method wherein the protein-wasting immunogen is P antigen from *P. anaerobius* and the antibody in the eggs includes IgY immunoglobulin in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs and that the method comprises distributing the dried entire contents of the harvested eggs uniformly in animal feed or water, supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to said protein-wasting immunogens to inhibit the adherence of said protein wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

The claimed invention in claim 15 differs from the teaching of the reference only in that the method wherein the protein-wasting immunogen is CS antigen from *C. sticklandii* and the antibody in the eggs includes IgY immunoglobulin in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs and that the method comprises distributing the dried entire contents of the harvested eggs uniformly in animal feed or water, supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to said protein-wasting immunogens to inhibit the adherence of said protein wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

The claimed invention in claim 16 differs from the teaching of the reference only in that the method wherein the protein-wasting immunogen is CA antigen from *C. aminophilium* and the antibody in the eggs includes IgY immunoglobulin in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs and that the method comprises distributing the dried entire contents of the harvested eggs uniformly in animal feed or water, supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to said protein-wasting immunogens to inhibit the adherence of said protein wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

Krause *et al* teach rumen bacteria such as *Peptostreptococcus anaerobius, Closteridium sticklandii,* and *Clostridium aminophilium* rob cattle of nutrients by the process of deamination; these culprits are identified by RNA sequencing. Krause *et al* teach amino acid deamination in the rumen is a nutritionally wasteful process that often produces excess ammonia and reduces the growth of livestock (See entire document, abstract, in particular). The excess ammonia is converted to urea (see page 815, column 1, in particular). Krause *et al* teach cattle fed with the antibiotic mononsin have decreased ammonia production and that this decrease was correlated with a decline in the amount of 16S rRNA that hybridized with probes for *P. anaerobius* and *C. sticklandii* but not *C. aminophilium* (See page 819, column 1, second paragraph, in particular). The feed additive of monensin does not entirely counteract the wasteful process of amino acid deamination by said bacteria (See abstract, in particular). Krause *et al* further teach that since the total protein intake of the cows was 630 g per day, it appeared that *Clostridium aminophilium* alone might be wasting approximately 9% of the feed protein (See page 820, column 1 first paragraph, in particular).

The '098 patent teaches that IgY are found in the yolk, while IgM and IgA antibodies are found only in the white which is the albumin (See column 5, lines 54-57, in particular). The '098 patent further teaches that adhesion of microorganisms to host cells surface glycoprotein receptor or basement membranes serves as an essential steps in the pathogenesis of diseases. If there is no adhesion, there is no disease (See column 6, line 56 bridging column 7, line 1-10, in particular). The '098 patent teaches egg antibodies such as IgY can be raised against any bacteria or certain portions of bacteria such as the pilus of *E. coli*. The reference antibodies prevent *E. coli*. from adhering to the rumen of intestinal track of the food animal such as dairy cattle and milking goats, beef cattle, sheep, deer, buffalo and yaks (See column 7, lines 11-19, claims 4 of '098 patent, in particular). The '098 patent further teaches the advantages of egg antibodies are numerous: Chicken antibodies do not react with mammalian complement, Fc receptors, protein A or protein G. Yolk antibodies show great acid and heat resistance. Extraction of yolk antibodies can be performed even on a large scale without costly investment. Concentrating the antibody from egg yolk is a relatively straightforward process. The antibody is not harmed by pasteurization. The FDA regards egg antibody as a food rather than a drug and has granted GRAS (generally accepted as safe) status thereto. Thus, there would be no problem with consumption of milk from dairy cattle treated with egg yolk antibodies, and no mandatory milk-withholding period, in sharp contrast to antibiotics (See paragraph bridging column 5 and 6, in particular).

The '489 patent teaches that egg antibodies are more resistant to degradation by gastric acidity when they are prepared from whole egg as compared to purified antibodies from the yolk (See column 2, lines 36-39, in particular). The '489 patent further teaches that egg antibodies (IgY) are effective in decreasing the adhesion of enterotoxigenic *E. coli*. onto enterocytes within the intestinal tract and thereby increasing feed conversion and body weight gain in food animal such as piglets and calves (See column 2, lines 49-61, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the immunogen *E. coli*. as taught by the '895 patent or the '489 patent for the immunogens such as *P. anaerobius, C. sticklandii,* and *C. aminophilium* that are responsible for protein wasting in food animal as taught by Krause *et al* by inoculating female birds in or about to reach their egg laying age with the said protein wasting immunogen, harvesting the eggs laid by the birds after a period of time sufficient to permit the production of antibody in the bird and eggs laid by the birds, drying the whole egg preparation containing IgY from the yolk and IgM and IgA from the white as taught by the '489 patent and distributing and

supplying the resulting dried entire contents of said harvested eggs as an feed additive or as a solution such as milk to livestock to prevent the adherence of *P. anaerobius, C. sticklandii,* or *C. aminophilium* in the intestinal tract of the animal as a method of promoting the growth of food animal taught by the '895 patent, the '489 patent, Krause *et al* and the '089 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to combine the references because Krause *et al* teach that *P. anaerobius, C.sticklandii,* and *C. aminophilium* are responsible for nutrition depletion and the growth of livestock (See abstract, column 9, line 43-47; column 3, line 19-27, in particular). The '895 patent teaches the method of making bird antibody to any bacteria of interest is particularly advantageous because the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27) and the bird antibody against the immunogen of interest as a food additive is effective as a method of preventing the immunogen from adhering to the rumen or intestinal tracts of livestock (See abstract, and claims of '895, in particular). The '098 patent further teaches the advantages of egg antibodies are numerous: Chicken antibodies do not react with mammalian complement, Fc receptors, protein A or protein G. Yolk antibodies show great acid and heat resistance. Extraction of yolk antibodies can be performed even on a large scale without costly investment. Concentrating the antibody from egg yolk is a relatively straightforward process. The antibody is not harmed by pasteurization. The FDA regards egg antibody as a food rather than a drug and has granted GRAS (generally accepted as safe) status thereto. Thus, there would be no problem with consumption of milk from dairy cattle treated with egg yolk antibodies, and no mandatory milk-withholding period, in sharp contrast to antibiotics (See paragraph bridging column 5 and 6, in particular). The '489 patent teaches that advantage of whole egg preparation is that the antibodies are more resistant to degradation by gastric acidity as compared to purified antibodies from the yolk (See column 2, lines 36-39, in particular). The '489 patent further teaches that egg antibodies (IgY) are effective in decreasing the adhesion of bacteria such as enterotoxigenic *E. coli*. onto enterocytes within the intestinal tract (See column 2, lines 49-61, in particular).

2. Claims 19-24 and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892), US Pat No 5,585,098 (Dec 1996, PTO 1449) and US Pat No 5,741,489 (April 1998, PTO 892) as applied to claims 14-16 above and further in view of US Pat 6,086,878 (of record, Jul 2000, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

The combined teachings of the '895 patent, Krause *et al*, the '098 patent and the '489 patent have been discussed supra. The '489 patent further teaches antibody can be mixed with a carrier such as fine ground corn and then mixed with the feed (See column 5, line 1-2, in particular).

The claimed invention in claims 19, 21, 23, 27, 29 and 31 differs from the combined teachings of the references only in that the method includes: providing a dry feed carrier material, drying the entire contents of the harvested eggs by coating the carrier material with said entire contents of the harvested eggs, distributing said carrier material coated with said entire contents of the harvested eggs in animal feed or water and supplying the carrier material coated with said entire contents of the harvested eggs and animal feed or water to substantially prevent adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

The claimed invention in claims 20, 22, 24, 28, 30 and 32 differs from the combined teachings of the references only in that the method wherein the dry feed carrier material is selected from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food or animal feed rations. The entire content of the egg can be sprayed directly onto food pellets (animal feed) and supplying the food pellets coated with the entire content of the egg containing high antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46). The reference dried egg powder can be used in drinks, or as protein supplement (See column 9, lines 47-8, in particular). The '878 patent further teaches there is no need to separate the yolk from the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular). The '878 patent teach whole egg may be administered to the subject without drying if desired since the whole egg can be eaten raw (see column 9, lines 60-61, in particular).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the carrier such as fine ground corn as taught by the '489 patent for the soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp as taught by the '867 patent and spray the entire content of the egg containing IgY from the yolk, IgM and IgA from the white directly onto the carrier and then mixed with the feed as taught by the '489 patent or directly on the animal feed as taught by the '867 patent to inhibit *P. anaerobius, C.sticklandii,* and *C.aminophilium* from adhering to the rumen or intestinal tracts of food animals as a method of promoting the growth of food animals as taught by the '895 patent, Krause *et al*, the '098 patent and the '489 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to combine the references because the '867 patent teaches the carrier material such as soybean hulls, rice hulls and cottonseed hulls provide the fibrous material and provide adequate structural strength or integrity to the final feed pellets to effect stool normality (See column 3, lines 14-16, in particular). The '489 patent teaches IgY antibody can be mixed with a carrier such as fine ground corn and then mixed with feed (See column 5, line 1-2, in particular). The '878 patent teaches the entire content of the hyperimmunized spray-dried egg powder can be mixed directly with food or animal feed rations to achieve high antibody titers (See column 9, lines 37-46). Krause *et al* teach that *P. anaerobius, C.sticklandii,* and *C. aminophilium* are responsible for nutrition depletion and the growth of livestock (See abstract, column 9, line 43-47; column 3, line 19-27, in particular). The '895 patent teaches the method of making bird antibody to any bacteria of interest is particularly advantageous because the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27) and the bird antibody against the immunogen of interest as a food

additive is effective as a method of preventing the immunogen from adhering to the rumen or intestinal tracts of livestock (See abstract, and claims of '895, in particular). The '098 patent further teaches the advantages of egg antibodies are numerous: Chicken antibodies do not react with mammalian complement, Fc receptors, protein A or protein G. Yolk antibodies show great acid and heat resistance. Extraction of yolk antibodies can be performed even on a large scale without costly investment. Concentrating the antibody from egg yolk is a relatively straightforward process. The antibody is not harmed by pasteurization. The FDA regards egg antibody as a food rather than a drug and has granted GRAS (generally accepted as safe) status thereto. Thus, there would be no problem with consumption of milk from dairy cattle treated with egg yolk antibodies, and no mandatory milk-withholding period, in sharp contrast to antibiotics (See paragraph bridging column 5 and 6, in particular). The '489 patent teaches that advantage of whole egg preparation is that the antibodies are more resistant to degradation by gastric acidity as compared to purified antibodies from the yolk (See column 2, lines 36-39, in particular). The '489 patent further teaches that egg antibodies (IgY) are effective in decreasing the adhesion of bacteria such as enterotoxigenic *E. coli*. onto enterocytes within the intestinal tract (See column 2, lines 49-61, in particular). It is within the purview of one ordinary skill in the art at the time the invention was made to coat the animal feed or food pallets directly with the entire contents of the harvested egg containing IgY from the yolk, and IgM and IgA from the white as taught by the '878 patent or indirectly onto the carrier such as fine ground corn before supplying the carrier material coated with the IgY antibody with the animal feed as taught by the '489 patent. Thus the claimed invention is an obvious variation of the references teachings.

(11) Response to Argument

Claims Rejection - 35 USC § 103

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892), US Pat No 5,585,098 (Dec 1996, PTO 1449) and US Pat No 5,741,489 (April 1998, PTO 892).

Paragraph bridging page 10 and 11 of the brief, Appellant submits that there are insufficient teachings of these combined references to practice the methods of claims 14, 15 and 16. Tokoro ('895 patent) teaches a method of inhibiting diarrhea in animals with bird antibody IgY using the yolks, the albumin and the yolks of the eggs. This method is related to the use of

raw eggs by cattle herdpersons to treat scours (diarrhea in cattle caused by intestinal infection). The '895 patent (Tokoro) is directed to a specific antibody containing substance from eggs and method of production and use thereof for the prevention and treatment of colibacillosis and diarrhea in animals. The antibody is used as nutrition supplement, and as an additive to food for animals. Tokoro does not provides a teaching of a method promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein wasting immunogens, P antigen from *P. anaerobius*, CS antigen from *C. sticklandii*, and CA antigen from *C. aminophilium*.

Appellant' arguments filed 2/20/04 have been fully considered but are not found persuasive.

In response to Appellant' arguments that the '895 patent (Tokoro) does not provides a teaching of a method promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein wasting immunogens, P antigen from *P. anaerobius*, CS antigen from *C. sticklandii*, and CA antigen from *C. aminophilium*, this rejection would have been under 35 USC 102(b) if the '895 patent (Tokoro et al) teaches every limitation of the claims.

The '895 patent teaches a method of promoting the growth of food animals by preventing diarrhea (dietary protein wasting caused by diarrhea due to the presence of *E. coli*.) in livestock by inoculating an egg laying female birds such as hen against a selected immunogen such as bacteria *E. coli*. (See column 5, lines 29-30, in particular), after a period of time such as a few weeks after the inoculation, the reference hen becomes sensitive to the reference immunized immunogen and produces the specific antibody to the immunized immunogen in the yolk and the albumin of the eggs (See column 5, lines 47-60, column 6, 10-18, in particular). The reference method includes the steps of collecting the egg laid by the hen (See column 6, line 1, in particular), separating the antibody against the inoculated immunogen from the yolk or albumin or both which is the entire content of the egg (See column 6, lines 19-20, in particular), drying the separated egg antibody by the process such as spray drying or lyophilizing to from powder product (See column 6, line 24-25, in particular), distributing and supplying the resulting dried egg antibody product as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent teaches the method of making bird

antibody to any bacteria of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

The claimed invention in claim 14 differs from the teaching of the reference only in that the method wherein the protein-wasting immunogen is P antigen from *P. anaerobius* and the antibody in the eggs includes IgY immunoglobulin in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs and that the method comprises distributing the dried entire contents of the harvested eggs uniformly in animal feed or water, supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to said protein-wasting immunogens to inhibit the adherence of said protein wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

The claimed invention in claim 15 differs from the teaching of the reference only in that the method wherein the protein-wasting immunogen is CS antigen from *C. sticklandii* and the antibody in the eggs includes IgY immunoglobulin in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs and that the method comprises distributing the dried entire contents of the harvested eggs uniformly in animal feed or water, supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to said protein-wasting immunogens to inhibit the adherence of said protein wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

The claimed invention in claim 16 differs from the teaching of the reference only in that the method wherein the protein-wasting immunogen is CA antigen from *C. aminophilium* and the antibody in the eggs includes IgY immunoglobulin in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs and that the method comprises distributing the dried entire contents of the harvested eggs uniformly in animal feed or water, supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to said protein-wasting immunogens to inhibit the adherence of said protein wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

Krause *et al* teach rumen bacteria such as *Peptostreptococcus anaerobius, Closteridium sticklandii,* and *Clostridium aminophilium* rob cattle of nutrients by the process of deamination; these culprits are identified by RNA sequencing. Krause *et al* teach amino acid deamination in

the rumen is a nutritionally wasteful process that often produces excess ammonia and reduces the growth of livestock (See entire document, abstract, in particular). The excess ammonia is converted to urea (see page 815, column 1, in particular). Krause *et al* teach cattle fed with the antibiotic mononsin have decreased ammonia production and that this decrease was correlated with a decline in the amount of 16S rRNA that hybridized with probes for *P. anaerobius* and *C. sticklandii* but not *C. aminophilium* (See page 819, column 1, second paragraph, in particular). The feed additive of monensin does not entirely counteract the wasteful process of amino acid deamination by said bacteria (See abstract, in particular). Krause *et al* further teach that since the total protein intake of the cows was 630 g per day, it appeared that *Clostridium aminophilium* alone might be wasting approximately 9% of the feed protein (See page 820, column 1 first paragraph, in particular).

The '098 patent teaches that IgY are found in the yolk, while IgM and IgA antibodies are found only in the white which is the albumin (See column 5, lines 54-57, in particular). The '098 patent further teaches that adhesion of microorganisms to host cells surface glycoprotein receptor or basement membranes serves as an essential steps in the pathogenesis of diseases. If there is no adhesion, there is no disease (See column 6, line 56 bridging column 7, line 1-10, in particular). The '098 patent teaches egg antibodies such as IgY can be raised against any bacteria or certain portions of bacteria such as the pilus of *E. coli*. The reference antibodies prevent *E. coli*. from adhering to the rumen of intestinal track of the food animal such as dairy cattle and milking goats, beef cattle, sheep, deer, buffalo and yaks (See column 7, lines 11-19, claims 4 of '098 patent, in particular). The '098 patent further teaches the advantages of egg antibodies are numerous: Chicken antibodies do not react with mammalian complement, Fc receptors, protein A or protein G. Yolk antibodies show great acid and heat resistance. Extraction of yolk antibodies can be performed even on a large scale without costly investment. Concentrating the antibody from egg yolk is a relatively straightforward process. The antibody is not harmed by pasteurization. The FDA regards egg antibody as a food rather than a drug and has granted GRAS (generally accepted as safe) status thereto. Thus, there would be no problem with consumption of milk from dairy cattle treated with egg yolk antibodies, and no mandatory milk-withholding period, in sharp contrast to antibiotics (See paragraph bridging column 5 and 6, in particular).

The '489 patent teaches that egg antibodies are more resistant to degradation by gastric acidity when they are prepared from whole egg as compared to purified antibodies from the yolk (See column 2, lines 36-39, in particular). The '489 patent further teaches that egg antibodies

(IgY) are effective in decreasing the adhesion of enterotoxigenic *E. coli.* onto enterocytes within the intestinal tract and thereby increasing feed conversion and body weight gain in food animal such as piglets and calves (See column 2, lines 49-61, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the immunogen *E. coli.* as taught by the '895 patent or the '489 patent for the immunogens such as *P. anaerobius, C. sticklandii,* and *C. aminophilium* that are responsible for protein wasting in food animal as taught by Krause *et al* by inoculating female birds in or about to reach their egg laying age with the said protein wasting immunogen, harvesting the eggs laid by the birds after a period of time sufficient to permit the production of antibody in the bird and eggs laid by the birds, drying the whole egg preparation containing IgY from the yolk and IgM and IgA from the white as taught by the '489 patent and distributing and supplying the resulting dried entire contents of said harvested eggs as an feed additive or as a solution such as milk to livestock to prevent the adherence of *P. anaerobius, C. sticklandii,* or *C. aminophilium* in the intestinal tract of the animal as a method of promoting the growth of food animal taught by the '895 patent, the '489 patent, Krause *et al* and the '089 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to combine the references because Krause *et al* teach that *P. anaerobius, C.sticklandii,* and *C. aminophilium* are responsible for nutrition depletion and the growth of livestock (See abstract, column 9, line 43-47; column 3, line 19-27, in particular). The '895 patent teaches the method of making bird antibody to any bacteria of interest is particularly advantageous because the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27) and the bird antibody against the immunogen of interest as a food additive is effective as a method of preventing the immunogen from adhering to the rumen or intestinal tracts of livestock (See abstract, and claims of '895, in particular). The '098 patent further teaches the advantages of egg antibodies are numerous: Chicken antibodies do not react with mammalian complement, Fc receptors, protein A or protein G. Yolk antibodies show great acid and heat resistance. Extraction of yolk antibodies can be performed even on a large scale without costly investment. Concentrating the antibody from egg yolk is a relatively straightforward process. The antibody is not harmed by pasteurization. The FDA regards egg antibody as a food rather than a drug and has granted GRAS (generally accepted as safe) status thereto. Thus, there would be no problem with consumption of milk from

dairy cattle treated with egg yolk antibodies, and no mandatory milk-withholding period, in sharp contrast to antibiotics (See paragraph bridging column 5 and 6, in particular). The '489 patent teaches that advantage of whole egg preparation is that the antibodies are more resistant to degradation by gastric acidity as compared to purified antibodies from the yolk (See column 2, lines 36-39, in particular). The '489 patent further teaches that egg antibodies (IgY) are effective in decreasing the adhesion of bacteria such as enterotoxigenic *E. coli*. onto enterocytes within the intestinal tract (See column 2, lines 49-61, in particular).

At page 12 first paragraph of the Brief, Appellant submits that Krause et al discloses that amino acid degradation in the rumen of animals is nutritionally wasteful and produces more ammonia than the bacteria in the rumen can utilize. The excess ammonia is concerted by the animal into urea and discharged into the environment as environmental pollution. The feed additive monensin decreases ammonia accumulation in the rumen. Krause et al discovered that monesin inhibited growth of *P. anaerobius* and *C. sticklandii* in the rumen of animal but did not inhibit *C. aminophilium*. The result was the reduction in the amount of ammonia in the rumen and reduction of environmental pollution. There is no teaching that monensin prevents adherence of a targeted immunogen in the intestinal tract of an animal thereby inhibiting its colony growth.

Appellant' arguments filed 2/20/04 have been fully considered but are not found persuasive.

In response to appellant's argument that there is no teaching that monensin prevents adherence of a targeted immunogen in the intestinal tract of an animal thereby inhibiting its colony growth, there would have been no motivation for making chicken antibodies that bind to immunogen *P. anaerobius* and *C. sticklandii* and *C. aminophilum* to prevent the adherence of said immunogen for the claimed method if the antibiotic monensin is so effective for reducing the number of *P. anaerobius* and *C. sticklandii* and *C. aminophilum* from colonizing the rumen of food animal. In fact, Krause *et al* teach rumen bacteria such as *P. anaerobius, C. sticklandii, and C. aminophilium* rob cattle of nutrients by the process of deamination; these culprits are identified by RNA sequencing. Krause *et al* teach amino acid deamination in the rumen is a nutritionally wasteful process that often produces excess ammonia and reduces the growth of livestock (See entire document, abstract, in particular). The excess ammonia is converted to urea (see page 815, column 1, in particular). Krause *et al* teach cattle fed with the antibiotic mononsin have decreased ammonia production and that this decrease was correlated with a decline in the amount

of 16S rRNA that hybridized with probes for *P. anaerobius* and *C. sticklandii* but not *C. aminophilium*. (See page 819, column 1, second paragraph, in particular). The feed additive of monensin does not entirely counteract the wasteful process of amino acid deamination by said bacteria (See abstract, in particular). Krause *et al* teach that since the total protein intake of the cows was 630 g per day, it appeared that *Clostridium aminophilium* alone might be wasting approximately 9% of the feed protein (See page 820, column 1 first paragraph, in particular).

The '098 patent teaches that IgY are found in the yolk, while IgM and IgA antibodies are found only in the white which is the albumin (See column 5, lines 54-57, in particular). The '098 patent further teaches that adhesion of microorganisms to host cells surface glycoprotein receptor or basement membranes serves as an essential steps in the pathogenesis of diseases. If there is no adhesion, there is no disease (See column 6, line 56 bridging column 7, line 1-10, in particular). The '098 patent teaches egg antibodies such as IgY can be raised against any bacteria or certain portions of bacteria such as the pilus of *E. coli*. The reference antibodies prevent *E. coli*. from adhering to the rumen of intestinal track of the food animal such as dairy cattle and milking goats, beef cattle, sheep, deer, buffalo and yaks (See column 7, lines 11-19, claims 4 of '098 patent, in particular). The '098 patent further teaches the advantages of egg antibodies are numerous: Chicken antibodies do not react with mammalian complement, Fc receptors, protein A or protein G. Yolk antibodies show great acid and heat resistance. Extraction of yolk antibodies can be performed even on a large scale without costly investment. Concentrating the antibody from egg yolk is a relatively straightforward process. The antibody is not harmed by pasteurization. The FDA regards egg antibody as a food rather than a drug and has granted GRAS (generally accepted as safe) status thereto. Thus, there would be no problem with consumption of milk from dairy cattle treated with egg yolk antibodies, and no mandatory milk-withholding period, in sharp contrast to antibiotics (See paragraph bridging column 5 and 6, in particular).

The '489 patent teaches that egg antibodies are more resistant to degradation by gastric acidity when they are prepared from whole egg as compared to purified antibodies from the yolk (See column 2, lines 36-39, in particular). The '489 patent further teaches that egg antibodies (IgY) are effective in decreasing the adhesion of enterotoxigenic *E. coli*. onto enterocytes within the intestinal tract and thereby increasing feed conversion and body weight gain in food animal such as piglets and calves (See column 2, lines 49-61, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the immunogen *E. coli*. as taught by the '895 patent or the '489

patent for the immunogens such as *P. anaerobius, C. sticklandii,* and *C. aminophilium* that are responsible for the protein wasting in food animal as taught by Krause *et al* for making egg antibodies to *P. anaerobius, C. sticklandii,* and *C. aminophilium* with the expectation that the egg antibodies that binds specifically to *P. anaerobius, C. sticklandii,* and *C. aminophilium* when mixed with the animal feed would have prevented the adhesion of said *P. anaerobius, C. sticklandii,* and *C. aminophilium* to the rumen or intestinal tracts of food animals as a method of promoting the growth of food animals. The strongest rationale for combining references is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent that some advantage or expected beneficial result would have been produced by their combination *In re Sernaker* 17 USPQ 1, 5-6 (Fed. Cir. 1983), see MPEP 2144.

At page 13 first paragraph of the Brief, Appellant submits that Coleman discloses a method of using egg antibody preparations to prevent and treat mastitis in diary cattle and milk producing animals. The preparation is limited to IgY antibodies which are administered to the animal to lower milk somatic cell count. Coleman recognizes that the laying hen transfers all antibodies isotypes found in the egg, i.e., IgY, IgM and IgA antibodies. The yolk contains only IgY while IgM and IgA are found only in the white. Coleman separates the yolk from the albumin. There is no teaching in Coleman to combine the yolk and albumin. The enhanced binding of IgY due to the IgM and IgA antibodies is not recognized by Coleman.

Appellant' arguments filed 2/20/04 have been fully considered but are not found persuasive.

One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. *In re Keller,* 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145. In response to Appellant's argument that there is no teaching in Coleman to combine the yolk and albumin, the '895 patent teaches a method of promoting the growth of food animals by preventing diarrhea (dietary protein wasting caused by diarrhea due to the presence of *E. coli.*) in livestock by inoculating an egg laying female birds such as hen against a selected immunogen such as bacteria *E. coli.* (See column 5, lines 29-30, in particular), after a period of time such as a few weeks after the inoculation, the reference hen becomes sensitive to the reference immunized immunogen and produces the specific antibody to the immunized

immunogen in the yolk and the albumin of the eggs (See column 5, lines 47-60, column 6, 10-18, in particular). The reference method includes the steps of collecting the egg laid by the hen (See column 6, line 1, in particular), separating the antibody against the inoculated immunogen from the yolk or albumin or both which is the entire content of the egg (See column 6, lines 19-20, in particular), drying the separated egg antibody by the process such as spray drying or lyophilizing to from powder product (See column 6, line 24-25, in particular), distributing and supplying the resulting dried egg antibody product as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent teaches the method of making bird antibody to any bacteria of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

At page 13 second paragraph of the Brief, Appellant submits that the '489 patent (Pimentel) discloses a method for increasing feed conversion efficiency in mammal with a diet containing an antibody produced by using the enzyme urease as the antigen. The '489 patent (Pimentel) states that chicken antibodies are generally known to protect the recipient against bacteria infections. No antibody has been shown to increase feed conversion efficient. Col. 2, lines 59-63. The '489 patent (Pimentel) is limited to the use of an antibody against the enzyme urease to obtain increased feed utilization and body weight gain in animals. There is no teaching of a method of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

Appellant' arguments filed 2/20/04 have been fully considered but are not found persuasive.

The '489 patent teaches that egg antibodies are more resistant to degradation by gastric acidity when they are prepared from whole egg as compared to purified antibodies from the yolk (See column 2, lines 36-39, in particular). The '489 patent further teaches that egg antibodies (IgY) are effective in decreasing the adhesion of enterotoxigenic *E. coli*. onto enterocytes within

the intestinal tract and thereby increasing feed conversion and body weight gain in food animal such as piglets and calves (See column 2, lines 49-61, in particular).

The '098 patent teaches that IgY are found in the yolk, while IgM and IgA antibodies are found only in the white which is the albumin (See column 5, lines 54-57, in particular). The '098 patent further teaches that adhesion of microorganisms to host cells surface glycoprotein receptor or basement membranes serves as an essential steps in the pathogenesis of diseases. If there is no adhesion, there is no disease (See column 6, line 56 bridging column 7, line 1-10, in particular). The '098 patent teaches egg antibodies such as IgY can be raised against any bacteria or certain portions of bacteria such as the pilus of *E. coli*. The reference antibodies prevent *E. coli*. from adhering to the rumen of intestinal track of the food animal such as dairy cattle and milking goats, beef cattle, sheep, deer, buffalo and yaks (See column 7, lines 11-19, claims 4 of '098 patent, in particular). The '098 patent further teaches the advantages of egg antibodies are numerous: Chicken antibodies do not react with mammalian complement, Fc receptors, protein A or protein G. Yolk antibodies show great acid and heat resistance. Extraction of yolk antibodies can be performed even on a large scale without costly investment. Concentrating the antibody from egg yolk is a relatively straightforward process. The antibody is not harmed by pasteurization. The FDA regards egg antibody as a food rather than a drug and has granted GRAS (generally accepted as safe) status thereto. Thus, there would be no problem with consumption of milk from dairy cattle treated with egg yolk antibodies, and no mandatory milk-withholding period, in sharp contrast to antibiotics (See paragraph bridging column 5 and 6, in particular).

The '895 patent teaches a method of promoting the growth of food animals by preventing diarrhea (dietary protein wasting caused by diarrhea due to the presence of *E. coli*.) in livestock by inoculating an egg laying female birds such as hen against a selected immunogen such as bacteria *E. coli*. (See column 5, lines 29-30, in particular), after a period of time such as a few weeks after the inoculation, the reference hen becomes sensitive to the reference immunized immunogen and produces the specific antibody to the immunized immunogen in the yolk and the albumin of the eggs (See column 5, lines 47-60, column 6, 10-18, in particular). The reference method includes the steps of collecting the egg laid by the hen (See column 6, line 1, in particular), separating the antibody against the inoculated immunogen from the yolk or albumin or both which is the entire content of the egg (See column 6, lines 19-20, in particular), drying the separated egg antibody by the process such as spray drying or lyophilizing to from powder product (See column 6, line 24-25, in particular), distributing and supplying the resulting dried

egg antibody product as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent teaches the method of making bird antibody to any bacteria of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

Krause *et al* teach rumen bacteria such as *Peptostreptococcus anaerobius, Closteridium sticklandii,* and *Clostridium aminophilium* rob cattle of nutrients by the process of deamination; these culprits are identified by RNA sequencing. Krause *et al* teach amino acid deamination in the rumen is a nutritionally wasteful process that often produces excess ammonia and reduces the growth of livestock (See entire document, abstract, in particular). The excess ammonia is converted to urea (see page 815, column 1, in particular). Krause *et al* teach cattle fed with the antibiotic mononsin have decreased ammonia production and that this decrease was correlated with a decline in the amount of 16S rRNA that hybridized with probes for *P. anaerobius* and *C. sticklandii* but not *C. aminophilium* (See page 819, column 1, second paragraph, in particular). The feed additive of monensin does not entirely counteract the wasteful process of amino acid deamination by said bacteria (See abstract, in particular). Krause *et al* teach that since the total protein intake of the cows was 630 g per day, it appeared that *Clostridium aminophilium* alone might be wasting approximately 9% of the feed protein (See page 820, column 1 first paragraph, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the immunogen *E. coli.* as taught by the '895 patent or the '489 patent for the immunogens such as *P. anaerobius, C. sticklandii,* and *C. aminophilium* that are responsible for the protein wasting in food animal as taught by Krause *et al* for making egg antibodies to *P. anaerobius, C. sticklandii,* and *C. aminophilium* with the expectation that the egg antibodies that binds specifically to *P. anaerobius, C. sticklandii,* and *C. aminophilium* when mixed with the animal feed would have prevented the adhesion of said *P. anaerobius, C. sticklandii,* and *C. aminophilium* to the rumen or intestinal tracts of food animals as a method of promoting the growth of food animals. The strongest rationale for combining references is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent that some advantage or expected

beneficial result would have been produced by their combination *In re Sernaker* 17 USPQ 1, 5-6 (Fed. Cir. 1983), see MPEP 2144.

One having ordinary skill in the art would have been motivated to combine the references because Krause *et al* teach that the culprits that rob cattle of nutrients are *Peptostreptococcus anaerobius, Closteridium sticklandii,* and *Clostridium aminophilium* and they are responsible for nutrition depletion and the growth of livestock (See entire document, abstract, in particular). The '895 patent teaches the method of making bird antibody to any bacteria of interest is particularly advantageous because the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27) and the bird antibody against the immunogen of interest as a food additive is effective as a method of preventing the immunogen from adhering to the rumen or intestinal tracts of livestock (food animal). The '098 patent teaches the advantages of egg yolk antibodies are numerous. Chicken antibodies do not react with mammalian complement, Fc receptors, protein A or protein G. Yolk antibodies show great acid and heat resistance. Extraction of yolk antibodies can be performed even on a large scale without costly investment. Concentrating the antibody from egg yolk is a relatively straightforward process. The antibody is not harmed by pasteurization. The FDA regards egg antibody as a food rather than a drug and has granted GRAS (generally accepted as safe) status thereto. Thus, there would be no problem with consumption of milk from dairy cattle treated with egg yolk antibodies, and no mandatory milk-withholding period, in sharp contrast to antibiotics. The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg (the entire content) (See column 2, lines 36-39, in particular).

In the paragraph bridging page 13 and 14 of the brief, Appellant submits that there are no motivating directions or suggestions in these references that would impel one skilled in the art to produce the claimed method. There is no teaching of a method of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability the ability of the immunogen to multiply.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of

primary and secondary references. *In re Nomiya*, 184 USPQ 607 (CPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In this case, The '895 patent teaches a method of promoting the growth of food animals by preventing diarrhea (dietary protein wasting caused by diarrhea due to the presence of *E. coli*.) in livestock by inoculating an egg laying female birds such as hen against a selected immunogen such as bacteria *E. coli*. (See column 5, lines 29-30, in particular), after a period of time such as a few weeks after the inoculation, the reference hen becomes sensitive to the reference immunized immunogen and produces the specific antibody to the immunized immunogen in the yolk and the albumin of the eggs (See column 5, lines 47-60, column 6, 10-18, in particular). The reference method includes the steps of collecting the egg laid by the hen (See column 6, line 1, in particular), separating the antibody against the inoculated immunogen from the yolk or albumin or both which is the entire content of the egg (See column 6, lines 19-20, in particular), drying the separated egg antibody by the process such as spray drying or lyophilizing to from powder product (See column 6, line 24-25, in particular), distributing and supplying the resulting dried egg antibody product as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent teaches the method of making bird antibody to any bacteria of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

The claimed invention in claim 14 differs from the teaching of the reference only in that the method wherein the protein-wasting immunogen is P antigen from *P. anaerobius* and the antibody in the eggs includes IgY immunoglobulin in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs and that the method comprises distributing the dried entire contents of the harvested eggs uniformly in animal feed or water, supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to said protein-wasting immunogens to inhibit the adherence of said

protein wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

The claimed invention in claim 15 differs from the teaching of the reference only in that the method wherein the protein-wasting immunogen is CS antigen from *C. sticklandii* and the antibody in the eggs includes IgY immunoglobulin in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs and that the method comprises distributing the dried entire contents of the harvested eggs uniformly in animal feed or water, supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to said protein-wasting immunogens to inhibit the adherence of said protein wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

The claimed invention in claim 16 differs from the teaching of the reference only in that the method wherein the protein-wasting immunogen is CA antigen from *C. aminophilium* and the antibody in the eggs includes IgY immunoglobulin in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs and that the method comprises distributing the dried entire contents of the harvested eggs uniformly in animal feed or water, supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to said protein-wasting immunogens to inhibit the adherence of said protein wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

Krause *et al* teach rumen bacteria such as *Peptostreptococcus anaerobius, Closteridium sticklandii,* and *Clostridium aminophilium* rob cattle of nutrients by the process of deamination; these culprits are identified by RNA sequencing. Krause *et al* teach amino acid deamination in the rumen is a nutritionally wasteful process that often produces excess ammonia and reduces the growth of livestock (See entire document, abstract, in particular). The excess ammonia is converted to urea (see page 815, column 1, in particular). Krause *et al* teach cattle fed with the antibiotic mononsin have decreased ammonia production and that this decrease was correlated with a decline in the amount of 16S rRNA that hybridized with probes for *P. anaerobius* and *C. sticklandii* but not *C. aminophilium* (See page 819, column 1, second paragraph, in particular). The feed additive of monensin does not entirely counteract the wasteful process of amino acid deamination by said bacteria (See abstract, in particular). Krause *et al* further teach that since the total protein intake of the cows was 630 g per day, it appeared that *Clostridium aminophilium*

alone might be wasting approximately 9% of the feed protein (See page 820, column 1 first paragraph, in particular).

The '098 patent teaches that IgY are found in the yolk, while IgM and IgA antibodies are found only in the white which is the albumin (See column 5, lines 54-57, in particular). The '098 patent further teaches that adhesion of microorganisms to host cells surface glycoprotein receptor or basement membranes serves as an essential steps in the pathogenesis of diseases. If there is no adhesion, there is no disease (See column 6, line 56 bridging column 7, line 1-10, in particular). The '098 patent teaches egg antibodies such as IgY can be raised against any bacteria or certain portions of bacteria such as the pilus of *E. coli*. The reference antibodies prevent *E. coli*. from adhering to the rumen of intestinal track of the food animal such as dairy cattle and milking goats, beef cattle, sheep, deer, buffalo and yaks (See column 7, lines 11-19, claims 4 of '098 patent, in particular). The '098 patent further teaches the advantages of egg antibodies are numerous: Chicken antibodies do not react with mammalian complement, Fc receptors, protein A or protein G. Yolk antibodies show great acid and heat resistance. Extraction of yolk antibodies can be performed even on a large scale without costly investment. Concentrating the antibody from egg yolk is a relatively straightforward process. The antibody is not harmed by pasteurization. The FDA regards egg antibody as a food rather than a drug and has granted GRAS (generally accepted as safe) status thereto. Thus, there would be no problem with consumption of milk from dairy cattle treated with egg yolk antibodies, and no mandatory milk-withholding period, in sharp contrast to antibiotics (See paragraph bridging column 5 and 6, in particular).

The '489 patent teaches that egg antibodies are more resistant to degradation by gastric acidity when they are prepared from whole egg as compared to purified antibodies from the yolk (See column 2, lines 36-39, in particular). The '489 patent further teaches that egg antibodies (IgY) are effective in decreasing the adhesion of enterotoxigenic *E. coli*. onto enterocytes within the intestinal tract and thereby increasing feed conversion and body weight gain in food animal such as piglets and calves (See column 2, lines 49-61, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the immunogen *E. coli*. as taught by the '895 patent or the '489 patent for the immunogens such as *P. anaerobius, C. sticklandii,* and *C. aminophilium* that are responsible for the protein wasting in food animal as taught by Krause *et al* for making egg antibodies to *P. anaerobius, C. sticklandii,* and *C. aminophilium* with the expectation that the egg antibodies that binds specifically to *P. anaerobius, C. sticklandii,* and *C. aminophilium* when

mixed with the animal feed would have prevented the adhesion of said *P. anaerobius, C. sticklandii,* and *C. aminophilium* to the rumen or intestinal tracts of food animals as a method of promoting the growth of food animals. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to combine the references because Krause *et al* teach that *P. anaerobius, C.sticklandii,* and *C. aminophilium* are responsible for nutrition depletion and the growth of livestock (See abstract, column 9, line 43-47; column 3, line 19-27, in particular). The '895 patent teaches the method of making bird antibody to any bacteria of interest is particularly advantageous because the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27) and the bird antibody against the immunogen of interest as a food additive is effective as a method of preventing the immunogen from adhering to the rumen or intestinal tracts of livestock (See abstract, and claims of '895, in particular). The '098 patent further teaches the advantages of egg antibodies are numerous: Chicken antibodies do not react with mammalian complement, Fc receptors, protein A or protein G. Yolk antibodies show great acid and heat resistance. Extraction of yolk antibodies can be performed even on a large scale without costly investment. Concentrating the antibody from egg yolk is a relatively straightforward process. The antibody is not harmed by pasteurization. The FDA regards egg antibody as a food rather than a drug and has granted GRAS (generally accepted as safe) status thereto. Thus, there would be no problem with consumption of milk from dairy cattle treated with egg yolk antibodies, and no mandatory milk-withholding period, in sharp contrast to antibiotics (See paragraph bridging column 5 and 6, in particular). The '489 patent teaches that advantage of whole egg preparation is that the antibodies are more resistant to degradation by gastric acidity as compared to purified antibodies from the yolk (See column 2, lines 36-39, in particular). The '489 patent further teaches that egg antibodies (IgY) are effective in decreasing the adhesion of bacteria such as enterotoxigenic *E. coli*. onto enterocytes within the intestinal tract (See column 2, lines 49-61, in particular). The strongest rationale for combining references is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent that some advantage or expected beneficial result would have been produced by their combination *In re Sernaker* 17 USPQ 1, 5-6 (Fed. Cir. 1983), see MPEP 2144.

Claims Rejection - 35 USC § 103

Claims 19-24 and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892), US Pat No 5,585,098 (Dec 1996, PTO 1449) and US Pat No 5,741,489 (April 1998, PTO 892) as applied to claims 14-16 above and further in view of US Pat 6,086,878 (of record, Jul 2000, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

At page 14 of the Brief, Appellant submits that claims 17-24 depend on claims 14, 15 and 16. Claims 17-24 include the process of providing a dry feed carrier material. The carrier material is coated with the entire dried contents of the eggs separated from the shells. The remarks concerning the'895 patent (Tokoro), Karuse et al, the'098 patent (Coleman) and the '489 patent (Pemental) are applicable to claims 17-24. The '878 patent (Adalsteinsson) discloses a method of administering to animals an effective amount of a gastrointestinal neuro-modulator antibody to neutralize the neuro-modulator. The egg is dried into an egg powder. An example of drying is spray drying. The dried egg powder can be mixed with animal rations or sprayed directed onto food pellets col. 9, lines 31-39. This is a mixing process wherein dry powder is mixed with animal rations which include food pellets. Applicants coat a carrier material with the entire contents of the harvested eggs. The coated carrier material is distributed into the animal feed. The carrier materials are a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grain and beet pulp.

Appellant' arguments filed 2/20/04 have been fully considered but are not found persuasive.

Appellant's argument with respect to claims 17-18 is moot in view of the canceling claims 17-18 by amendment filed 9/23/03. Therefore, only claims 19-24 include the process of providing a dry feed carrier material.

In response to Appellant's argument that appellant coats a carrier material with the entire contents of the harvested eggs instead of the egg is dried into egg power and then mixed with animal ration, it is noted that claims 19-24 depend from claims 14-16. The step E of Claims 14-16 requires the separated entire contents of harvested eggs be drying before distributing the dried entire contents of harvested eggs uniformly in animal feed. The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed

to coat directly onto food pellets (animal feed) and supplying the food pellets coated with the entire content of the egg to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46); the reference dried egg powder can be used in drinks, protein supplement (See column 9, lines 47-8, in particular). The '878 patent further teaches there is no need to separate the yolk from the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular). The '878 patent teach whole egg may be administered to the subject without drying if desired since the whole egg can be eaten raw (see column 9, lines 60-61, in particular). In fact, the specification on page 25 discloses whole egg can be dispensed in water supplies, or a dried format as whole powdered egg (See example 21).

In response to Appellant's argument that the carrier material is coated with the entire dried contents of the eggs separated from the shells, the '489 patent teaches antibody can be mixed with a carrier such as fine ground corn and then mixed with feed (See column 5, line 1-2, in particular). It is within the purview of one ordinary skill in the art at the time the invention was made to dry the entire contents of the harvested egg containing IgY from the yolk and IgM and IgA from the white by the process of sprayed drying to form egg powders, coating the entire contents of the egg onto food pellets directly as taught by the '878 patent or indirectly onto the carrier such as fine ground corn before supplying the carrier material coated with the entire content of the egg with the animal feed as taught by the '489 patent. Thus the claimed invention in claims 19-24 is obvious variation of the references teachings.

At page 15 second paragraph of the Brief, Appellant submits that the '867 patent (Betz et al) teach soy hulls, cottonseed hulls, and rice hulls. However, these fibrous materials are not coated with egg antibody.

Appellant' arguments filed 2/20/04 have been fully considered but are not found persuasive.

In response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145.

The '489 patent teaches antibody can be mixed with a carrier such as fine ground corn and then mixed with feed (See column 5, line 1-2, in particular).

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food or animal feed rations. The entire content of the egg can be sprayed directly onto food pellets (animal feed) and supplying the food pellets coated with the entire content of the egg containing high antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46). The reference dried egg powder can be used in drinks, or as protein supplement (See column 9, lines 47-8, in particular). The '878 patent further teaches there is no need to separate the yolk from the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular). The '878 patent teach whole egg may be administered to the subject without drying if desired since the whole egg can be eaten raw (see column 9, lines 60-61, in particular).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the carrier such as fine ground corn as taught by the '489 patent for the soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp as taught by the '867 patent and spray the entire content of the egg containing IgY from the yolk, IgM and IgA from the white onto the carrier and then mixed with the feed as taught by the '489 patent or directly on the animal feed as taught by the '867 patent for a method of promoting the growth of animals by inhibiting the immunogen *P. anaerobius, C.sticklandii,* and *C.aminophilium* from adhering to the rumen or intestinal tracts of food animals as taught by the '895 patent, Krause *et al*, the '098 patent and the '489 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to combine the references because the '867 patent teaches the carrier material such as soybean hulls, rice hulls and cottonseed hulls provide the fibrous material and provide adequate structural strength or integrity

to the final feed pellets to effect stool normality (See column 3, lines 14-16, in particular). The '489 patent teaches IgY antibody can be mixed with a carrier such as fine ground corn and then mixed with feed (See column 5, line 1-2, in particular). The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food or animal feed rations. The entire content of the egg can be sprayed directly onto food pellets (animal feed) and supplying the food pellets coated with the entire content of the egg containing high antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46). Krause *et al* teach that the culprits that rob cattle of nutrients are *Peptostreptococcus anaerobius, Closteridium sticklandii,* and *Clostridium aminophilium* and they are responsible for nutrition depletion and the growth of livestock (See entire document, abstract, in particular). The '895 patent teaches the method of making bird antibody to any bacteria of interest is particularly advantageous because the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27) and the bird antibody against the immunogen of interest as a food additive is effective as a method of preventing the immunogen from adhering to the rumen or intestinal tracts of livestock (food animal), which inherently promotes the growth of livestock by decreasing diarrhea such as wasting dietary protein caused by the presence of protein-wasting immunogen (See abstract, and claims of '895, in particular). The '098 patent teaches the advantages of egg yolk antibodies are numerous. Chicken antibodies do not react with mammalian complement, Fc receptors, protein A or protein G. Yolk antibodies show great acid and heat resistance. Extraction of yolk antibodies can be performed even on a large scale without costly investment. Concentrating the antibody from egg yolk is a relatively straightforward process. The antibody is not harmed by pasteurization. The FDA regards egg antibody as a food rather than a drug and has granted GRAS (generally accepted as safe) status thereto. Thus, there would be no problem with consumption of milk from dairy cattle treated with egg yolk antibodies, and no mandatory milk-withholding period, in sharp contrast to antibiotics. The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg (the entire content) (See column 2, lines 36-39, in particular). It is within the purview of one ordinary skill in the art at the time the invention was made to coat the animal feed or food pallets directly with the entire contents of the harvested egg as taught by the '878 patent or indirectly onto the carrier such as fine ground corn before supplying the carrier material coated with the IgY antibody with the animal feed as taught by the '489 patent. Thus the claimed invention is an obvious variation of the references teachings.

At page 15 and 16 of the Brief, Appellant submits that claims 27-32 define the method of promoting the growth of food animal by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens, P antigen from *P. annerobius*, CS antigen from *C. sticklandii* and CA antigen from *C. aminophilium* by inhibiting the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of immunogens to multiply. The method does not include the step of drying the separate entire contents of the harvested eggs before the entire contents of the harvested eggs are coated on dry feed carrier material. The remarks concerning the'895 patent (Tokoro), Karuse et al, the'098 patent (Coleman) and the '489 patent (Pemental) are applicable to claims 27-32. The teachings of the '878 patent (Adlsteinsson et al) and the '867 patent (Betz et al) do not utilize a dry feed carrier material to dry mixed egg yolks and albumin having yolk IgY immunoglobulins combined with albumin IgM and IgA immunoglobulins coated on the dry feed carrier. The '878 patent (Adlsteinsson et al)'s dried egg powder mixed with animal feed rations does not dry the egg powder. Also, spraying dried egg powder on food pellets in oil does not dry the egg powder. Betz et al does not disclose drying of antibody yolk and albumin with soybean hulls, rice hulls or cottonseed hulls. The hull taught by the '867 patent (Betz et al) are not used to dry any feed materials.

Appellant' arguments filed 2/20/04 have been fully considered but are not found persuasive.

In response to Appellant's argument that "dry feed carrier material to dry mixed egg yolks and albumin having yolk IgY immunoglobulins combined with albumin IgM and IgA immunoglobulins coated on the dry feed carrier", it is noted that the features upon which applicant relies (i.e., dry feed carrier material *to dry mixed egg yolks and albumin having yolk IgY immunoglobulins combined with albumin IgM and IgA immunoglobulins*) are not recited in the rejected claim(s). Step E of Claims 27, 29 and 31 merely requires providing a dry feed carrier material; step F of Claims 27, 29 and 31 simply requires coating said dry feed carrier material with the separated entire contents of the harvested eggs. Further, the disclosure as filed fails to teach the dry feed carrier material is to be use for *drying mixed egg yolks and albumin having yolk IgY immunoglobulins combined with albumin IgM and IgA immunoglobulins.*

The combined teachings of the '895 patent, Krause *et al*, the '098 patent and the '489 patent have been discussed supra. The '489 patent further teaches antibody can be mixed with a

carrier such as fine ground corn and then mixed with the feed (See column 5, line 1-2, in particular).

The claimed invention in claims 19, 21, 23, 27, 29 and 31 differs from the combined teachings of the references only in that the method includes: providing a dry feed carrier material, drying the entire contents of the harvested eggs by coating the carrier material with said entire contents of the harvested eggs, distributing said carrier material coated with said entire contents of the harvested eggs in animal feed or water and supplying the carrier material coated with said entire contents of the harvested eggs and animal feed or water to substantially prevent adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

The claimed invention in claims 20, 22, 24, 28, 30 and 32 differs from the combined teachings of the references only in that the method wherein the dry feed carrier material is selected from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food or animal feed rations. The entire content of the egg can be sprayed directly onto food pellets (animal feed) and supplying the food pellets coated with the entire content of the egg containing high antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46). The reference dried egg powder can be used in drinks, or as protein supplement (See column 9, lines 47-8, in particular). The '878 patent further teaches there is no need to separate the yolk from the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular). The '878 patent teach whole egg may be administered to the subject without drying if desired since the whole egg can be eaten raw (see column 9, lines 60-61, in particular).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the carrier such as fine ground corn as taught by the '489 patent for the soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp as taught by the '867 patent and spray the entire content of the egg containing IgY from the yolk, IgM and IgA from the white directly onto the carrier and then mixed with the feed as taught by the '489 patent or directly on the animal feed as taught by the '867 patent to inhibit *P. anaerobius, C.sticklandii,* and *C.aminophilium* from adhering to the rumen or intestinal tracts of food animals as a method of promoting the growth of food animals as taught by the '895 patent, Krause *et al*, the '098 patent and the '489 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to combine the references because the '867 patent teaches the carrier material such as soybean hulls, rice hulls and cottonseed hulls provide the fibrous material and provide adequate structural strength or integrity to the final feed pellets to effect stool normality (See column 3, lines 14-16, in particular). The '489 patent teaches IgY antibody can be mixed with a carrier such as fine ground corn and then mixed with feed (See column 5, line 1-2, in particular). The '878 patent teaches the entire content of the hyperimmunized spray-dried egg powder can be mixed directly with food or animal feed rations to achieve high antibody titers (See column 9, lines 37-46). Krause *et al* teach that *P. anaerobius, C.sticklandii,* and *C. aminophilium* are responsible for nutrition depletion and the growth of livestock (See abstract, column 9, line 43-47; column 3, line 19-27, in particular). The '895 patent teaches the method of making bird antibody to any bacteria of interest is particularly advantageous because the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27) and the bird antibody against the immunogen of interest as a food additive is effective as a method of preventing the immunogen from adhering to the rumen or intestinal tracts of livestock (See abstract, and claims of '895, in particular). The '098 patent further teaches the advantages of egg antibodies are numerous: Chicken antibodies do not react with mammalian complement, Fc receptors, protein A or protein G. Yolk antibodies show great acid and heat resistance. Extraction of yolk antibodies can be performed even on a large scale without costly investment. Concentrating the antibody from egg yolk is a relatively straightforward process. The antibody is not harmed by pasteurization. The FDA regards egg antibody as a food rather than a drug and has granted GRAS (generally accepted as safe) status

thereto. Thus, there would be no problem with consumption of milk from dairy cattle treated with egg yolk antibodies, and no mandatory milk-withholding period, in sharp contrast to antibiotics (See paragraph bridging column 5 and 6, in particular). The '489 patent teaches that advantage of whole egg preparation is that the antibodies are more resistant to degradation by gastric acidity as compared to purified antibodies from the yolk (See column 2, lines 36-39, in particular). The '489 patent further teaches that egg antibodies (IgY) are effective in decreasing the adhesion of bacteria such as enterotoxigenic *E. coli.* onto enterocytes within the intestinal tract (See column 2, lines 49-61, in particular). It is within the purview of one ordinary skill in the art at the time the invention was made to coat the animal feed or food pallets directly with the entire contents of the harvested egg containing IgY from the yolk, and IgM and IgA from the white as taught by the '878 patent or indirectly onto the carrier such as fine ground corn before supplying the carrier material coated with the IgY antibody with the animal feed as taught by the '489 patent. Thus the claimed invention is an obvious variation of the references teachings.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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May 1, 2004

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Appendix A

14. (Previously Amended) A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is P antigen from *P.anaerobius*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with P antigen from *P.anaerobius*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to P antigen from *P.anaerobius*, said antibody in the eggs including 1gY immunoglobulins in the yolks of the eggs and IgM and lgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the eggshells;

E. Drying said separated entire contents of said harvested eggs;

F. Distributing said dried entire contents of said harvested eggs substantially uniformly in animal feed or water to provide antibody-containing animal feed or water; and

G. Supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens, to inhibit adherence of the protein-wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

15. (Previously Amended) A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CS antigen from *C.Sticklandii*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with CS antigen from *C.Sticklandii*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to CS antigen from *C.Sticklandii*, said antibody in the eggs including lgY immunoglobulins in the yolks of the eggs and IgM and lgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the eggshells;

E. Drying said separated entire contents of said harvested eggs;

F. Distributing said dried entire contents of said harvested eggs substantially uniformly in animal feed or water to provide antibody-containing animal feed or water; and

G. Supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens, to inhibit adherence of the protein-wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

16. (Previously Amended) A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CA antigen from *C.aminophilium*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with CA antigen from *C.aminophilium*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to CA antigen from *C.aminophilium*, said antibody in the eggs including lgY immunoglobulins in the yolks of the eggs and IgM and lgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;

E. Drying said separated entire contents of said harvested eggs;

F. Distributing said dried entire contents of said harvested eggs substantially uniformly in animal feed or water to provide antibody-containing animal feed or water; and

G. Supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens, to inhibit adherence of the protein-wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

19. (Previously Presented) The method of Claim 14 including: providing a dry feed carrier material, drying said entire contents of said harvested eggs by coating the carrier material with said entire contents of said harvested eggs, distributing said carrier material coated with said entire contents of said harvested eggs in animal feed or water, and supplying the carrier material coated with said entire contents of said harvested eggs and animal feed or water to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

20. (Previously Presented) The method of Claim 19 wherein: providing a dry feed carrier material from a group of materials including soybean hull, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

21. (Previously Presented) The method of Claim 15 including: providing a dry feed carrier material, drying said entire contents of said harvested eggs by coating the carrier material with said entire contents of said harvested eggs, distributing said carrier material coated with said entire contents of said harvested eggs in animal feed or water, and supplying the carrier material coated with said entire contents of said harvested eggs and animal feed or water to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

22. (Previously Presented) The method of Claim 21 wherein: providing a dry feed carrier material from a group of materials in duding soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

23. (Previously Presented) The method of Claim 16 including: providing a dry feed carrier material, drying said entire contents of said harvested eggs by coating the carrier material with said entire contents of said harvested eggs, distributing said carrier material coated with said entire contents of said harvested eggs in animal feed or water, and supplying the carrier material coated with said entire contents of said harvested eggs and animal feed or water to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

24. (Previously Presented) The method of Claim 23 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

27. (Previously Amended) A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is P antigen from *P.anaerobius*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with P antigen from *P.anaerobius*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to P antigen from *P.anaerobius*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the shells;

E. Providing a dry feed carrier material;

F. Coating said dry feed carrier material with the separated entire contents of said harvested eggs;

G. Distributing said carrier material coated with the entire contents of said harvested eggs substantially uniformly in animal feed; and

H. Supplying the resulting dry feed carrier material coated with the entire contents of said harvested eggs and animal feed to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

28. The method of Claim 27 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

29. (Previously Amended) A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CS antigen from *C.sticklandii*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with CS antigen from *C.sticklandii*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to CS antigen from *C.sticklandii*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the shells;

E. Providing a dry feed carrier material;

F. Coating said dry feed carrier material with the separated entire contents of said harvested eggs;

G. Distributing said carrier material coated with the entire contents of said harvested eggs substantially uniformly in animal feed; and

H. Supplying the resulting dry feed carrier material coated with the entire contents of said harvested eggs and animal feed to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

30. The method of Claim 29 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

31. (Previously Amended) A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CA antigen from *C.aminophilium*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with CA antigen from *C.aminophilium*;

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to CA antigen from *C.aminophilium*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the shells;

E. Providing a dry feed carrier material;

F. Coating said dry feed carrier material with the separated entire contents of said harvested eggs;

G. Distributing said carrier material coated with the entire contents of said harvested eggs substantially uniformly in animal feed; and

H. Supplying the resulting dry feed carrier material coated with the entire contents of said harvested eggs and animal feed to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

32. The method of Claim 31 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.